

REMARKS

Examiner's Interview

Applicants' representative thanks the Office for the courtesy and consideration extended to the undersigned and Applicants during the July 1, 2001 telephonic interview. The interview was helpful to Applicants and their representative in further clarifying the issues remaining in this application. During the interview, the Office indicated that new grounds of rejection under 35 U.S.C. § 112, second paragraph, were raised and that new claims 40-45 were withdrawn from consideration.

Formal Matters

Claims 1, 4, and 39 are pending in the application. Claims 1 and 4 are allowed. Claim 39 is amended to more particularly point out and distinctly claim the subject matter of Applicants' invention by reciting that the binding of NRG3 to each of the ErbB receptors is in the absence of the other receptors. Support for the amendment is found throughout the specification, such as, for example, at page 78, lines 8-22 and Fig. 6. No new matter is added by this amendment. The amendment is made to place the rejected claim in better form for consideration on appeal, should an appeal become necessary. The Examiner is respectfully requested to enter it.

Claims 40-45 were withdrawn from consideration as drawn to a non-elected invention during a telephonic interview held on July 1, 2001. Claims 40-45 are canceled without prejudice to later prosecution, such as in a continuation or divisional application.

Rejection Under 35 U.S.C. § 112, Second Paragraph, Withdrawn

The rejection of claims 1 and 4 under 35 U.S.C. § 112, second paragraph, for allegedly lacking antecedent basis was withdrawn in light of Applicants' clarification of the record.

The rejection of claims 1 and 4 under 35 U.S.C. § 112, second paragraph, for allegedly unclear metes and bounds of "an EGF-like domain" was withdrawn in light of Applicants'

arguments.

Applicants gratefully acknowledge the Examiner's consideration of Applicants' arguments and withdrawal of the rejections.

Rejection Under 35 U.S.C. §112, First Paragraph, Withdrawn

The rejection of claims 1 and 4 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement was withdrawn in light of Applicants' arguments.

Applicants gratefully acknowledge the Examiner's consideration of Applicants' arguments and withdrawal of the rejections.

Rejection Under 35 U.S.C. §112, Second Paragraph, New Grounds

Claim 39 was rejected as indefinite for recitation of the term "experimentally comparable conditions" as allegedly failing to apprise one of ordinary skill in the art of the scope of the invention. While not explicitly stated in the Office Action, Applicants assume that the rejection is made under 35 U.S.C. §112, second paragraph, and will discuss the rejection with that in mind. Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

The Finality of the Rejection Is Improper

The Office Action issued July 3, 2001 (Paper No. 6) introduced a new ground for rejection of new claim 39. This new ground for rejection was not warranted by the new claim because it claims substantially the same subject matter as the previously pending claims. Any limitations included in the amendments were ones which should reasonably have been expected to be claimed (see MPEP 706.7(a)). On those grounds, Applicants respectfully submit that the finality of the Action is premature and respectfully request that the finality be withdrawn.

The Rejection Is Improper

Applicants respectfully submit that the rejection of claim 39 for reciting "experimentally comparable conditions" is improper because the term is readily understood by one of ordinary

skill in the art and, therefore, adequately informs him of the invention's scope.

One of ordinary skill in the relevant art of protein chemistry is skilled in the art of biological experimentation and readily understands that a comparison of the binding characteristics between one set of proteins and a second set of proteins assumes that the binding experiments were performed under comparable conditions. Even without an explicit definition, the ordinarily skilled artisan would readily understand that a polypeptide of the invention of claim 39 that binds ErbB4 receptor but does not bind ErbB2 receptor or ErbB3 receptor, refers to a comparison of the binding to these receptors and, thus, refers to binding under comparable conditions. Thus, the scope of the invention is established and the rejection is improper. Withdrawal of the rejection is respectfully requested.

One of ordinary skill in the art is adequately guided by Applicants' originally filed specification to understand at least one non-limiting example of a binding experiment in which the binding of an NRG3 derivative is tested for binding to ErbB4 receptor, ErbB2 receptor, and ErbB3 receptor, each binding in the absence of the other receptors (see the specification at page 78, lines 8-22, and Fig. 6). Thus, the ordinarily skilled artisan, upon reading Applicants' claim, is guided by Applicants' specification coupled with general knowledge of the relevant art to understand the scope of Applicants' invention. As a result, Applicant respectfully submits that the rejection is improper and should be withdrawn, which action is requested.

For the above reasons, Applicants respectfully disagree with the Examiner's rejection of claim 39 as indefinite. Without conceding the correctness of the Examiner's position and merely to place the claim in condition or allowance and/or to reduce the issues on appeal, should an appeal become necessary, Applicants have amended claim 39 to recite that the binding characteristics of the claimed polypeptide comprise, in part, binding to ErbB4 receptor but not to ErbB2 receptor or ErbB3 receptor, wherein the binding to each receptor is in the absence of the other receptors. As noted above, support is found throughout the specification such as at page 78, lines 8-22, and Fig. 6. No new matter is added by the amendment. The Examiner is respectfully requested to enter the amendment because it complies with a formal requirement to

apprise one of ordinary skill in the art of the scope of the invention with respect to binding characteristics of NRG3. Nevertheless, the claim amendments are not to be construed as an agreement with the Examiner's position. Applicants reserve the right to prosecute any canceled subject matter at a later date. Applicants also point out that the amendment does not constitute an abandonment of any of the canceled subject matter.

Applicants submit that the rejection has been overcome and that claim 39 is in condition for allowance, which action is respectfully requested.

SUMMARY

Claims 1 and 4 are allowed.

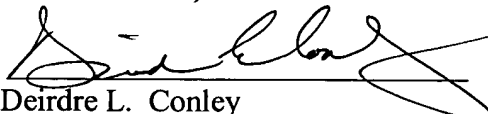
Claim 39 was rejected on new grounds. Applicants submit that the rejection on new grounds was improper and that the rejection was improper and should be withdrawn. The amendment to claim 39 is made merely to comply with a formal requirement, thereby making the amendment appropriate for entry into the claim. No new matter is added by the amendment. This amendment also presents the rejected claim in better form for consideration on appeal, should an appeal become necessary. For these reasons, the Examiner is respectfully requested to enter the amendment and allow claim 39.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is strongly encouraged to call the undersigned at the number indicated below.

This response/amendment is submitted with a transmittal letter, petition, and fees for a three month extension of time. In the unlikely event that this document is separated from the transmittal letter, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 39 is amended as follows, wherein strikeout in brackets [00] indicates deleted terminology and underling [00] indicates added terminology.

39. (Amended) An isolated polypeptide comprising an EGF-like domain, wherein the EGF-like domain consists of an amino acid sequence having at least 75% amino acid sequence identity to SEQ ID NO:4, and wherein the EGF-like domain has the binding characteristics of NRG3 comprising:

(a) binding to ErbB4 receptor but not to ErbB2 receptor or ErbB3 receptor [~~under experimentally comparable conditions~~] wherein the binding to each receptor is in the absence of the other receptors; and

(b) activation of ErbB4 receptor tyrosine phosphorylation.

✓
Cancel claims 40-45 as withdrawn from consideration, but without prejudice to later prosecution, such as the filing of a continuation or divisional application.